C. Remarks

The claims are 56-58, 60, 64, 66-68 and 74-82, with claim 74 being the sole independent claim. Claims 53 and 55 have been cancelled without prejudice or disclaimer. Claims 56-58, 60, 64, 66-68 and 74-82 have been amended as to formal matters. No new matter has been added. Reconsideration of the pending claims is respectfully requested.

Claims 53, 56, 58, 60, 64, 66-68 and 74-82 stand rejected under 35 U.S.C. §103(a) as being obvious over Bodmer (U.S. Patent No. 5,538,739) in view of GB 2,145,422 (Brich) and Reiners (U.S. Patent No. 4,879,402). Specifically, the Examiner alleges that "it would have been obvious to one of ordinary skill to purify the polymer of Bodmer et al using activated charcoal in view of the teaching in GB '422 to use a conventional purification technique and further in view of the teaching in Reiners et al that, in a method of making a polymer using Sn octoate, the beneficial effect of purification to clarity is achieved using activated charcoal". Applicant respectfully traverses this rejection.

At the outset, Applicant notes Bodmer's disclosure of microparticles containing octreotide and Brich's disclosure of a making a polylactide polymer using tin octoate as a catalyst. Applicant further notes Brich's disclosure that its polymer may be purified and isolated in a "conventional manner". Finally, Applicant notes Reiners' disclosure of polymer formation followed by filtration over active charcoal until a colorless product is obtained.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a

reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The presently cited combination of Bodmer, Brich and Reiners is deficient with regard to all three criteria.

First, there is no suggestion or motivation to combine the reference teachings. While Applicant acknowledges that Bodmer and Brich may be combined given their shared field of endeavor, i.e., pharmaceutical formulation, Reiners would not likely be combined with either of Bodmer and Brich as it is directed to the synthesis of a polymer useful for dental materials. As evidence of the unlikelihood of combination, there is the very different classification of Reiners from Bodmer and Brich.

Also weighing against combination is the fact that Brich discloses its own conventional purification technique, i.e., through the use of methylene dichloride, and does not suggest the product obtained by its process (1) needs catalyst removal at all or (2) needs any further purification. What is more, Reiners provides no motivation to combine it with the other cited references. In fact, not only does Reiners fail to disclose the use of activated charcoal to specifically remove a catalyst (Reiners instead purifies to clarity), but Reiners also fails to attach any importance to such a purification step. At column 13, lines 44-46, Reiners states the following: "A preceding filtration or purification by means of adsorbents, for example active charcoal, bleaching earth, silica gel or aluminum oxide, is possible" (emphasis added). Reiners' purification to clarity or until a colorless solution is formed is not demonstrative, then, of purification to remove a tin catalyst. As noted in Applicant's previous response, in fact, the presence of a tin catalyst has very little effect on color; accordingly, purification based solely on lack of color does not necessarily teach tin catalyst removal. As can be seen, the full extent of Reiners' disclosure is limited to the

potential, i.e., not required, use of activated charcoal to remove some impurities from a polymer synthesis reaction mixture.

Even if it were proper to combine the reference teachings (which Applicant does not concede), there is no reasonable expectation of success once combination is made. None of the cited references specifically discusses catalyst removal nor the importance thereof. None of the cited references provides any guidance in obtaining a polymer with a purity level (off-white to white in color; one or more metals having a concentration only of up to 10 ppm) like that of the polymer employed in the present invention. Accordingly, there is no reasonable guarantee that the purity level necessary to avoid undesirable local irritation reactions, instability of pharmaceutical formulation matrix, and accelerated drug release can be attained through purification via either of Brich or Reiners.

Finally, the cited combination of Bodmer, Brich and Reiners fails to teach or suggest all of the limitations of the present claims. Most importantly, none of the cited references teaches the limitation with regard to metal ion content. Contrary to the Examiner's position, it is not merely a matter of optimizing the degree of purity. Instead, it is a question of whether catalyst removal is performed at all. The Examiner alleges that "the goal of purification after making of a polymer is to remove all impurities, including the catalyst" - Applicant submits that such a statement is simply not true. Not all synthetic schemes contemplate complete end product purity; there certainly are circumstances under which such complete end product purity is not possible or desirable, i.e., catalyst removal too costly, elimination of unnecessary purification steps and hence extra process steps when a catalyst does not affect subsequent process steps, etc. Indeed, even Reiners suggests that end product purity may not be pursued in its column 13 characterization of filtration or purification as "possible". In any event, neither Brich nor Reiners discloses or

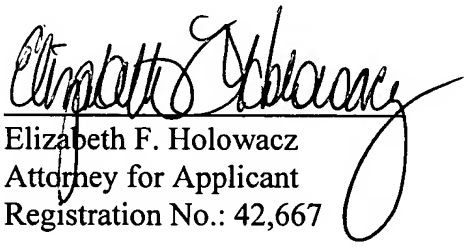
suggests that a tin catalyst is removed from the resulting polymer to the extent that less than 10 ppm of metal ion in cationic form is present. Accordingly, the advantageous effects of the present invention - avoidance of undesirable local irritation reactions, stability of pharmaceutical formulation matrix, and non-accelerated drug release - will not consistently be achieved by purification via either of Brich or Reiners since neither reference (nor Bodmer) sets forth the critical claim parameter, i.e., metal ion content.

For all of the above reasons, Applicant submits that the present invention is not rendered obvious by the cited combination of Bodmer, Brich and Reiners. In sum, there is no motivation to combine the cited references, and even when combined, there is no reasonable expectation of success and simply no teaching or suggestion of critical claim parameters. Accordingly, Applicant respectfully requests withdrawal of the §103 rejection.

This Amendment After Final Rejection is believed to place this application in condition for allowance. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100 or at the below listed address. All correspondence should continue to be directed to Novartis, Corporate Intellectual Property, One Health Plaza 104/3, East Hanover, NJ 07936-1080.

Respectfully submitted,



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